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### Remarks

Claims 1-25, 50, and 51 are pending in the present application.

Claims 1, 9, 17, and 50 are independent claims directed to stents comprising a latticed network of monofilaments.

Claims 18, 22, and 25 are independent claims directed to stents comprising a fenestrated walled surface.

Claim 51 is directed to a method for using a stent.

In this communication, claims 1, 9, 18, 22, 25, and 51 have been amended. In addition, new claims 52-57 are presented.

The amendment to claims 1, 9, and 51 is supported in the specification at, for example, paragraphs 38-40; Figures 4-9; and the claims as originally filed.

The subject matter of newly presented claims 52-55 is supported at, for example, paragraphs 38-43; and Figures 4-7.

The subject matter of claim 56 is supported at numerous locations throughout the specification and claims as originally filed, for example, at paragraphs 33, 34, and 38.

The subject matter of claim 57 is supported at numerous locations throughout the specification and claims as originally filed, for example, at paragraphs 45 and 50.

Upon entry of the current amendment, claims 1-25 and 50-57 will be in front of the Examiner for consideration. Reconsideration and allowance of the claims, as amended, and in light of the following remarks, are respectfully requested.

### Claim Rejections

Claims 1-3, 8-11, 16-25 and 51 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (U.S. Patent No. 6,569,191; referred to herein as "Hogan") in view of Stack et al. (International Publication No. WO 91/17789; referred to herein as "Stack").

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**Claims 1, 9, and 51**

The rejection with respect to claims 1, 9, and 51, is overcome by amendment.

Claims 1, 9, and 51, are amended to recite that the self-expanding stent is gamma-irradiated by exposure to gamma irradiation in an amount in the range of approximately 35 kGy to 75 kGy.

Neither Hogan nor Stack describes treating a stent with an amount of gamma irradiation in this recited range.

In view of this amendment, the rejection of claims 1, 9, and 51, and any claims which depend therefrom, is overcome. Applicants respectfully request that this rejection be withdrawn.

**Claim 17**

Claim 17 is also rejected under 35 USC 103(a) as being unpatentable over Hogan in view of Stack. Claim 17 recites a stent that includes a combination of specific features, including a controllable in vivo lifetime.

Applicants traverse this rejection because a stent having a controllable in vivo lifetime and the specific combination of features recited in claim 17 would not have been obvious in view of Hogan or Stack, taken individually or in combination.

Specifically, the combination of features recited in claim 17 include a: plurality of braided monofilaments comprising poly-L-lactide polymers, a cylindrical sleeve having a controllable in vivo lifetime; and the self-expanding stent being annealed and gamma-irradiated.

Hogan describes that memory in a stent can be imparted by fixing an elastic member to the stent body. Much of the Hogan reference explains how elastic members (strips or bands) can be integrated into a stent, how the elastic members provide a structural "memory" feature to the stent, and how stents having these elastic members can be inserted into and function in the body. Hogan is silent with regard to treating the stent using gamma irradiation or annealing.

The combination of Stack with Hogan does not result in a stent having the specific combination of features recited in claim 17. Stack is directed to bioabsorbable

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stents (see abstract), and includes some separate portions that mention features of claim 17. In the one example that Stack sets forth (pages 25-26), poly-L-lactide monofilaments were used. After the filaments were wound to form the stent, annealing was carried out at 140°C for 15 minutes. At page 19, Stack describes the possibility of exposing a stent to gamma radiation.

Despite these portions of the Stack reference, the reference has not been shown to specifically teach or suggest that it is desirable to use the combination of annealing *and* gamma irradiation of the specific stent recited in claim 17, having the recited number of braided monofilaments and comprising poly-L-lactide. As compared to Stack, the invention as recited in claim 17 realizes the benefits of the combination of annealing *and* gamma irradiation in controlling the in vivo lifetime of a stent that specifically contains poly-L-lactide and has the recited braided configuration.

Overall, the Hogan and Stack references have not been shown to specifically teach or suggest the combination of features found in claim 17, including a braided stent having filaments as recited, comprising poly-L-lactide, having a controllable in vivo lifetime, and that is both annealed and gamma-irradiated. The rejection of claim 17 as obvious over Hogan in view of Stack is not supported, and Applicants respectfully request that the rejection be withdrawn.

#### Claims 18, 22, & 25

Independent claims 18, 22, and 25 all recite: a bioresorbable, self-expanding stent comprising... a fenestrated walled surface.

The Office Action asserts that Hogan teaches a stent having a “fenestrated” wall.

Applicants respectfully disagree with this assessment for a number of different reasons.

First, Hogan does not describe either textually or in the illustrations, stents as having “fenestrations” or as being “fenestrated.”

Further, to the Applicants’ knowledge of common usage of the term “fenestrated,” a stent having a “fenestrated walled surface” is distinct from a stent

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wherein a sheath is formed from helically wound monofilament, as described throughout Hogan.

Further, in paragraphs 49 and 50 of Applicants' specification, for example, stents having a walled surface with a plurality of fenestrations are described and distinguished from stents formed from wound threads. Paragraph 50 of Applicants' specification also describes a method of making a stent with a fenestrated walled surface. Given this context, a stent with a "fenestrated walled surface" is not seen to be described anywhere in Hogan.

Therefore, Hogan is not sufficient as a primary reference in an obviousness rejection, as it does not teach a "fenestrated walled surface." Applicants respectfully request that the rejection of claims 18, 22, and 25, and the claims that depend therefrom be withdrawn.

#### Claim 50

The Office action rejects claim 50 under 35 U.S.C. 103(a) as being unpatentable over Hogan in view of Stack, and further in view of Turnlund et al. (U.S. Patent No. 5,629,077; herein "Turnlund"). Applicants traverse this rejection because the cited combination of references fails to teach or suggest a stent having a controllable in vivo lifetime and other specific combinations of features recited in claim 50.

Claim 50 recites a stent that includes the following features:

a latticed network formed from monofilaments comprising poly-L-lactide,  
a controllable in vivo lifetime of at least two weeks,  
and the stent being annealed and gamma-irradiated.

Hogan and Stack have been discussed above (see Applicants' arguments regarding claim 17). Those comments also apply to the rejection of claim 50. That is, the combination of Hogan and Stack has not been shown to specifically teach or suggest a stent having a combination of features that include a braided stent comprising filaments comprising poly-L-lactide, having a controllable in vivo lifetime, and that is both annealed and gamma-irradiated.

Turnlund fails to remedy the shortcomings of the Hogan and Stack references.

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Turnlund discusses a biodegradable mesh and film stent that is formed of a sheet of a composite mesh material formed of biodegradable high strength polymer fibers bonded together with a second biodegradable adhesive polymer and laminated on at least one side with a thin film of a third biodegradable polymer (see abstract). Turnlund discusses heating the stents during lamination at Col. 7, lines 30-35. Turnlund does not discuss treating the stents with the combination of annealing and gamma irradiation.

Relative to the rejection of claim 50, the Office action has not established that Turnlund teaches or suggests anything beyond what has already be taught by Hogan and Stack. Taken as such, Applicants respectfully request that the rejection of claim 50, on the stated grounds, be withdrawn.

In view of the present amendments and remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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